

### **REMARKS**

#### **Status of the Claims**

Claims 1-19 and 21 are currently pending in the application. Claims 1-45 stand rejected. The Examiner objects to the Title of the Invention. Claims 1-19 and 21 have been amended as set forth herein. Claims 20 and 22-45 have been cancelled herein. All amendments and cancellations are made without prejudice or disclaimer. No new matter has been added by way of the present amendments. Specifically, the amendments to the claims are to remove the term "or a hydrate of those." Claim 8 is further amended to depend from claim 7 instead of claim 6. Further, the amendment of claim 21 is also supported by the specification at, for instance, page 104, line 8 to page 105, line 2. Reconsideration is respectfully requested.

#### **Objection to the Title of the Invention**

The Examiner states that the Title of the Invention is not descriptive. Although Applicants disagree, to expedite prosecution, the Title of the Invention has been amended herein without prejudice or disclaimer to recite, "Heterocyclic macrolide pharmaceutical agent, a method of producing the same and use of the same." No new matter is entered into the specification by way of this amendment. Applicants believe this Title is descriptive of the disclosed invention.

The Examiner also objects to claim 8. (*See*, Office Action of June 8, 2007, at page 2, hereinafter, "Office Action"). The Examiner states that claim 8 depends on claim 6 and that claim 8 recites a substituent X<sub>1</sub> which is not described in claim 6. Applicants have amended

claim 8 to now depend from claim 7. As pointed out by the Examiner, claim 7 does provide a definition of the variable  $X_1$ .

Reconsideration and withdrawal of the objections to the Title of the Invention and claim 8 are respectfully requested.

### **Rejections Under 35 U.S.C. § 112, Second Paragraph**

Claims 20-38 and 42-45 stand rejected under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. (See, Office Action, at pages 2-3). Claims 20, 22-38 and 42-45 have been cancelled herein without prejudice or disclaimer, thus obviating the rejection of these claims. Applicants traverse the rejection as to the remaining claims as set forth herein.

The Examiner states that claim 21 is indefinite for reciting “a pharmaceutical composition.” The Examiner states that this is vague because the claim does not also recite a pharmaceutically acceptable carrier, excipient or diluent.

Although Applicants do not agree that claim 21 is indefinite, to expedite prosecution, claim 21 has been amended herein without prejudice or disclaimer to recite, in part, “and a pharmaceutically acceptable carrier.” Support for this amendment may be found at, for instance, page 104, line 8 to page 105, line 2 of the specification, which discloses formulation/administration alternatives for the presently claimed compositions.

Reconsideration and withdrawal of the indefiniteness rejection of claim 21 are respectfully requested.

## **Rejections Under 35 U.S.C. § 112, First Paragraph**

### Enablement

Claims 1-21 and 39-45 stand rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement. (*See*, Office Action, at pages 3-9). Claims 20 and 39-45 have been cancelled herein without prejudice or disclaimer, thus obviating the rejection as to these claims. Applicants traverse the rejection as to the remaining claims as set forth herein.

The Examiner states that claims 1-21 lack support in the specification for hydrate forms of the claimed compounds. The Examiner states that there is no disclosure of the formation of a hydrate of any of the compounds claimed.

Although Applicants do not agree that claims 1-19 and 21 lack enablement support in the specification, to expedite prosecution, claims 1-19 and 21 have been amended herein without prejudice or disclaimer to remove the phrase “or a hydrate of them.” Thus, as amended, the claims no longer recite the phrase upon which the present rejection is based.

Reconsideration and withdrawal of the enablement rejection of claim 1-19 and 21 are respectfully requested.

### Written Description

Claims 22-45 stand rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. (*See*, Office Action, at pages 9-11). Claims 22-45 have been cancelled herein without prejudice or disclaimer, thus obviating the rejection of these claims based on a lack of written description support in the specification.

### **Rejections Under 35 U.S.C. § 101**

Claims 42-45 stand rejected under 35 U.S.C. § 101 because they allegedly are directed to non-statutory subject matter. (*See*, Office Action, at page 12). Claims 42-45 have been cancelled herein without prejudice or disclaimer, thus obviating the rejection of these claims based on a lack of statutory subject matter.

### **Rejections Under the Obviousness-Type Double Patenting Doctrine**

Claims 1-45 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-71 and 73-92 of Mizui et al., U.S. Patent No. 7,026,352, hereinafter referred to as "Mizui et al." (*See*, Office Action, at page 12). Although Applicants do not agree that the present claims are obvious in light of the disclosure of Mizui et al., to expedite prosecution, Applicants will submit at a later time a properly executed Terminal Disclaimer with respect to the term of Mizui et al., thus obviating the rejection. Applicants intend to submit this Terminal Disclaimer before the Examiner acts on the present amendment. The Examiner is respectfully requested to contact Applicants' representatives at the number below if a Terminal Disclaimer has not yet been filed and the present amendment must be acted upon by the Examiner.


**CONCLUSION**

If the Examiner has any questions or comments, please contact Thomas J. Siepmann, Ph.D., Registration No 57,374, at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: November 8, 2007

Respectfully submitted,

By 

Marc S. Weiner  
Registration No.: 32,181  
BIRCH, STEWART, KOLASCH & BIRCH, LLP  
8110 Gatehouse Road  
Suite 100 East  
P.O. Box 747  
Falls Church, Virginia 22040-0747  
(703) 205-8000  
Attorney for Applicants

